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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,367	03/10/2004	Janel E. Young	ETH5095CIP	4470

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EXAMINER
FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
06/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/797,367	YOUNG ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,30-32,34 and 39-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28, 30-32, 34 and 39-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of request for extension of time, request for continued examination under 37 CFR 1.114, amendment and remarks, all filed 03/31/09 Claims 1-14, 16-19, 21-25, 27 and 33 are canceled. Claims 28, 30, 32 and 39 are amended. Claims 28, 30-32, 34 and 39-41 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/31/09 has been entered.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 28, 30-32, 34 and 39-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

5. The recitation that delivery vehicle consists of tranilast was not envisioned. Applicant has indicated that support for the amendment could be found on 5, lines 24, 25; page 10, lines 14-18. But, the sections of the specification applicant relies upon does not provide support for the amendment.

6.

7. Claims 28, 30-32, 34 and 39-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 28 recites the limitation "the potassium … salt of Tranilast" in lines 34 and 35. There is insufficient antecedent basis for this limitation in the claim. "The potassium … salt of Tranilast" is the first occurrence of the phrase and there is thus not antecedent basis for "the potassium … salt of Tranilast."

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 28, 31, 32 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al. (US 6,239,177).

11. Claim 28 is amended say that the delivery vehicle consists of tranilast or analog. Claims 30 and 39 are also amended to define what biodegradable polymers are.

Mori discloses external tranilast composition (abstract; column 2, lines 39-43) comprising tranilast, dissolution medium (column3, line 54 to column 4, line 24), polymers such as propylene glycol (column 4, line 65), polyvinyl alcohol, polyethylene glycol, polyacrylate, naturally occurring polysaccharides, gelatin, gum Arabic, polyester (column 5, lines 22-27, 62) with the suggestion that these polymer can be used alone or in combination of two or more thereof (column 5, lines 27 and 28); Mori's composition is in the form of a patch or film (column 5, lines 13, 58-65; Examples 1 and 2) meeting claim 28; the composition of Mori and the polymer carrier meet the requirements of claim 28, and in the form of a patch or film as recited in claims 28 and 39 are met when the barrier comprises gelatin or species of starch as in Example 1. Claims 31 and 32 are directed to the properties/characteristic of the device so that the composition of Mori meets these claims.

Response to Arguments

12. Applicant's arguments filed 3/31/09 have been fully considered but they are not persuasive.

13. Applicant argues that amended claim 28 is limited to a vehicle that consists of Tranilast. Applicant's argument is not persuasive to overcome the rejection because the comprising

language of the claim is still open and does not exclude other components that may be present in the composition of Mori.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 28, 30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. (US 6,239,177 B1).

Mori is described above as describing the composition in claims 28, 31, 32 and 39. When the barrier in Mori is polyester (see column 5, line 62), then claim 30 is rendered obvious because the lactides, glycolides and caprolactones of claim 30 are all polyesters. Mori describes that it has been found in the prior art that tranilast is found in the skin of keloid patients at about

8-10 μg/g (column 2, line 47) and suggests that tranilast concentration on skin after application to the skin would be higher that that previously observed (column 2, lines 57-60) but does not disclose the concentration of the tranilast in the composition in claim 34. However, given the general teaching of Mori regarding the use of the tranilast to treat keloid or allergic dermatitis, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success in using an amount of the tranilast in the composition that would be effective to treat keloid or allergic dermatitis.

Response to Arguments

17. Applicant's arguments filed 3/31/09 have been fully considered but they are not persuasive.

18. Applicant argues that Mori is deficient because Mori's vehicle does not consist of tranilast as argued above. The examiner disagrees. As noted in paragraph 9 above of this action, amended claim 28 is limited to a vehicle that consists of Tranilast. Applicant's argument is not persuasive to overcome the rejection because the comprising language of the claim is still open and does not exclude other components that may be present in the composition of Mori.

19.

20. Claims 28, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. (US 6,239,177 B1) in view of Pope et al. (US 5,948,822).

Mori has been described above for disclosing the composition in claims 28, 31, 32 and 39. Mori's composition does not contain further therapeutic agents recited in claims 40 and 41. However, Pope discloses antiproliferative agent that reduces the hyperproliferative keloid formation (column 3, lines 12-34; column 5, lines 1, 2, 6 and 7). Given the general teachings of

Mori and Pope, one having ordinary skill in the art at the time the invention was made would have a reasonable expectation of success that the combined compositions of Mori and Pope would be effective to reduce hyperproliferative keloid formation. See also *in re Kerkhoven*.

Response to Arguments

21. Applicant's arguments filed 3/31/09 have been fully considered but they are not persuasive.

22. Applicant argues that the amended claim 28 is directed to a composition comprising a vehicle that consists of Tranilast and one of skill in the art would not have been motivated to eliminate the solubilizer for the tranilast. Applicant's argument is not persuasive to overcome the rejection because the composition of claim 28 is comprising and the comprising language of the claim does not exclude solubilizer and the skilled artisan, therefore, does not have to exclude the solubilizer.

23. Claims 28, 30, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaji et al. (US 6,407,139) in view of M'Timkulu et al. (US 5,578,310).

Isaji discloses composition comprising tranilast (abstract; column 2, lines 25-52; column 3, lines 22-24), additives such as excipients, disintegrators, binders, lubricants, diluents, buffers, isotonicity agents, antiseptics, moistening agents, emulsifiers, dispersing agents, stabilizing agents and dissolving aids (column 4, lines 34-39) and polymers such as lactic acid, polyacrylamide, lactic acid-glycolic acid copolymer and polyvinylpyrrolidone when a sustained release preparation is desired (column 5, lines 1-7); the composition is formulated into dosage forms such as powders, granules, fine granules, dry syrup, tablets, **ointments**, injections and eye drops (column 4, lines 30-33) with ointment and eye drops representing non-systemic

administration although the claimed invention is directed to a delivery device for which the composition of Isaji is. Claim 31 and 32 are directed to the properties/characteristic of the device so that the composition of Isaji meets these claims. When polymers are lactides, claim 30 is met as the barrier and also meeting the barrier of claim 28. Isaji does not teach the forms of the product, namely, foam or film or fiber or filament. However, when an ointment is topical applied it is generally spread into film according to claims 1 and 16 of US 5,578,310. Therefore, taking the teaching of the prior art, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that topically applying the ointment of Isaji would expected form a film as contemplated for topical delivery of tranilast.

Response to Arguments

24. Applicant's arguments filed 3/31/09 have been fully considered but they are not persuasive.

25. Applicant argues that Isaji does not teach a composition containing delivery vehicle that consists of Tranilast in biodegradable polymer in the form of fibers, film, foam and filaments. The examiner disagrees. The comprising language of the claims is open. Furthermore, the rejection is not anticipatory but a rejection under 35 USC in which a combination of references, Isaji in view of M'Timkulu et al. (US 5,578,310) where M'Timkulu teaches that topical application spreads formulations such as ointment which forms a film after the spreading application.

26. Claims 28, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaji et al. (US 6,407,139) in view of M'Timkulu et al. (US 5,578,310) and further in view of Akhtar et al. (US 5,432,163).

Isaji has been shown above to render obvious claims 28, 30, 31 and 32. Isaji acknowledges in the background that tranilast is used to treat conditions such as allergic disorders such as bronchial asthma, allergic rhinitis, **atopic dermatitis** and allergic conjunctivitis, and cutaneous disorders such as keloid and hypertrophic scar (column 2, lines 6-16). Isaji does not teach the presence other therapeutic agents with the tranilast. However, Akhtar discloses antiproliferative for treating **atopic dermatitis** (column 3, lines 45-57). Given the general teachings of Isaji and Akhtar, one having ordinary skill in the art at the time the invention was made would have a reasonable expectation of success that topical application of the ointment of Isaji would be effective to treat atopic dermatitis according to Akhtar.

Response to Arguments

27. Applicant's arguments filed 3/31/09 as it applies to the current rejections have been fully considered but they are not persuasive.

28. Applicant argues that Isaji does not teach the forms of the product as recited in the amended claims. The examiner disagrees. The rejection is not an anticipatory rejection. However, it is known art that topical application of an ointment leads to the formation of film according to claims 1 and 16 of US 5,578,310 so that formation of film upon topical application would be reasonably expected.

29. Applicant also argues that the claimed composition comprises vehicle that consists of Tranilast and the composition of Aktar does not. The examiner disagrees because the comprising language of the claims is open.

Double Patenting

30. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

31. Claims 28, 30-32 and 39-41 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-19, 21-24, 27-41 of copending Application No. 10/780,452 (US 20050181023) in view of Chandrasekar et al. ("Platelets and Restenosis," in Journal of the American College of Cardiology, Vo. 35, No. 2, 2000, pp 555-562) or Miyazawa et al. ("Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat," in Journal of Cardiovascular Pharmacology, Vol. 30, no. 2, Aug. 1997).

The compositions of copending claims 14-19, 21-24, 27-41 of application number 10/780,452 contain Pemirolast instead of Tranilast. Both the Pemirolast and the tranilast have the functionality of inhibiting post-operative adhesion. It is however known in the art that both

tranilast and pemirolast are antiallergic agents known to reduce intimal thickening as disclosed by Chandrasekar (first full paragraph, left column of page 559) and Miyazawa (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use pemirolast in place of tranilast with the expectation that the composition would reduce intimal thickening. One having ordinary skill in the art would have been motivated to use tranilast or pemirolast to reduce intimal thickening with the expectation to either would reduce intimal thickening.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

32. Applicant's arguments filed 3/31/09 have been fully considered but they are not persuasive.

33. Applicant states that the double patenting rejection should be considered in view of the amendment. The examiner has considered the amended claims and the co-pending claims in view of Chandrasekar et al. ("Platelets and Restenosis," in Journal of the American College of Cardiology, Vo. 35, No. 2, 2000, pp 555-562) or Miyazawa et al. ("Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat," in Journal of Cardiovascular Pharmacology, Vol. 30, no. 2, Aug. 1997) and still finds that the pending claims are obvious over the combined references.

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618